510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The	assigned	510(k)	number is:	

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888 Fax: +86 755 2658 2680

Contact Person:

Zhai Pei Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: September 27, 2010

2. Device Name:

DC-7 Diagnostic Ultrasound System DC-3/DC-3T Diagnostic Ultrasound System

Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN) 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

The DC-3/DC-3T Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color mode, PW mode, CW mode, Power mode, DirPower

mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.0 MHz to 12.0 MHz.

4. Intended Use:

The DC-3/DC-3T diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetrics, abdominal, pediatric, small parts(breast, thyroid, testicle, etc), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, intraoperative, urology, orthopedics, and musculoskeletal (conventional and superficial) exams.

5. Comparison with Predicate Device:

DC-3/DC-3T Diagnostic Ultrasound System is comparable with and substantially equivalent to the Mindray DC-7(K101041), Mindray DC-3/DC-3T (K091941) and Mindray M5(K102991) Diagnostic Ultrasound System. They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate device.

6. Non-clinical Tests:

DC-3/DC-3T Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, UD 3,IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37,IEC 60601-1-4,ISO 10993-1 and IEC 62304.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-3/DC-3T Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 10903 New Hampshire Avenue Document Mail Center - WO66-G609 Silver Spring, MD 20993-0002

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. % Ms. Susan D. Goldstein-Falk Official Correspondent mdi Consultants, Inc. 55 Northern Blvd., Suite 200 GREAT NECK NY 11021

NOV - 3 2010

Re: K102865

Trade/Device Name: DC-3/DC-3T Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYO, IYN, and ITX

Dated: September 30, 2010 Received: September 30, 2010

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-3/DC-3T Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>3C5A</u>	<u>6C2</u>	<u>7L5</u>
<u>6CV1</u>	<u>6LE7</u>	<u>7LT4</u>
<u>7L4A</u>	<u>6LB7</u>	D6-2
<u>7L6</u>	<u>3C1</u>	
10L4	<u>2P2</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,

David G. Brown, Ph.D.

Acting Director

Division of Radiological Devices
Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

K102865

Indications for Use

NOV - 3 2010

510(k) Number (if known):

Device Name: DC-3/DC-3T Diagnostic Ultrasound System

Indications For Use:

The DC-3/DC-3T diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetrics, abdominal, pediatric, small parts(breast, thyroid, testicle, etc), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, intraoperative, urology, orthopedics, and musculoskeletal (conventional and superficial) exams.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Z(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 5102 8 65

Page 1 of __1_

Diagnostic Ultrasound Indications for Use Form

DC-3/DC-3T Diagnostic Ultrasound System

Intended Use: Diagnostic utussound imaging or fluid flow analysis of the human body as follows:

Ctini	cal Application					Mode of C	Operation		
General (Track I Only)	Specific (Track: 1 & 3)	В	M.	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic						-		
	Petal	·P	₽	P		P	P	P	Note 1,2,3,4,5,6,7
	Abdominal	P	P	P	P	P	P	P	Note 1,2,3,4,5,6,7
	Intraoperative (specify)*	P	۵	P		P	P	P	Note 2,3,4.5.6
	intraoperative (Neuro)						*		
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,3,4,5,6,7
	Small organ(specify)""	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonstal Cephalic	P	P	P	P	P	P	P	Note 1,2,3,4,5,6
ete) maging	Adult Cephalic	P	P	P	Р	Р	P	P	Note 1,2,3,5,6
t Other	Trans-rectal	p	P	P		P	P	P	Note 2,3,4,5.6
	Trans-vaginal	P	_P	P		P	P	P	Note 2,3,5,6
	Trans-urethral								
	Trans-esoph (non-Card.)						-		
	Musculo-skeletal Conventional	P	P.	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	, р	р	Note 2,3,4,5,6
	intravascular								·
	Other (specify)***	р	P	P.		P	P	P	Note 1,2,3,4,5,6
	Cardiac Adult	p	Þ	P	p	P	Þ	À	Note 1,2,3,4,5,6
	Cardiac Pediatric	P	P	Р	P	Р	P	P	Note 1,2,3,4,5,6
Cardiac	Intravascular (Cardiac)	,	·····						}
	Trans-exoph (Cardine)								
	Intra-Cardiac								
cripheral	Peripheral Vascular	P	P	Р		Р	P	Р	Note 1,2,3,4,5,6
/ascular	Other (specify)								

N=new indication; P=previously cleared by FDA; E=sdded under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal; thoracio, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

** *Other use includes Urology.

Note i: Tissue Harmonie Imaging.

Note 2: Smart3D

Note 3: iScape

Noted: iBeam

Note5: Blopsy Guidance

Notes: Free Xros M.

Note7; 4D

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

DC-3/DC-3T Diagnostic Ultrasound System

3C5A

Intended Use; Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

(Clinical Application					Mode o	of Operation		The second second
General (Track i Only)	Specific (Track.) & 3)	В	М	PWD	ĊWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
· Provinces	Fetal	P	P	P		P	P	P	Note 1, 2, 3,5,6
	Abdominal	P	P	P		P	P	P	Note 1, 2, 3,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)		:	1	T				
	Laparoscopic			1					
	Pediatric	P	P	ρ		P	í þ	P	Note 1, 2, 3,5,6
	Small organ(specify)**								
Petal	Negnatal Cephalic			T					
maging	Adult Cephalia								THE SELECTION OF THE SE
& Other.	Trans-rectal			1					
i.	Trans-vaginal			1					
	Trans-urethral		,					.,	
	Trans-esoph.(non-Card.)								
1	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial		. ,	1					restitus.
	lotravescular	la tour				is anastr			
	Other (specify)***	₽	P	Р,		P	P	P	Note 1,2,3,5,6
	Cardisc Adult				7	1 0 0 1 1			
	Cardisc Pediatrie	1 "	1 *			-			
Cardiac	Intravascular (Cardiae)	1		T					
	Trans-esoph (Cardiac)			1			··		
	Intra-Cardiac			 					
Peripheral	Peripheral Vascular	P	P	P		P	P	P	Note 1, 2, 3,5,6
Vascular	Other (specify)		1	 		1.0			

N=now indication: P=previously cleared by FDA; E=added under Appendix E

Additional comments Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color + B, Power + PW +B.

- *Introperative includes abdominal, thorneid, and vascular etc.
- **Small organ-breast, thyroid, testes, etc.
- ***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Noto4: iBcam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

escription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

DC-3/DC-3T Diagnostic Ultrasound System

* 1	Clinical Application			311 141		Mode	of Operation		
General (Track i Only)	Specific (Track 1 & 3)	8	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal ·	P	P	P		P	P	p	Note2, 3,5,6
	Abdominal		¥						
	intraopezative (specify)*					-,			
	intrappensiive (Neuro)							81.525.584 Y	
	Laparoscopie							(1374	4
	Pediatric								
	Small organ(specify)**						8		
Fetal	Neonatal Cephalic								
lmaging	Adult Cephalic					1			
2 Other	Trans-rectal	₽	P	·P		P	Р	p.	Note2, 3,5,6
	Trans-vaginal	P	P	P	•	P	P	Ŷ	Note2, 3,5,6
	Trans-weibral	-4	- 17.5						
;	Trans-esoph (non-Card.)						*	John J.	
ta jak	Musculo-skeletal Conventional		14) i					
	Musculo-skeletal Superficial								
ì	htravascular				1			in a second	
	Other (specify)***	P	P	P		P	P	P	Note 2,3,5,6
	Cardiac Adult	Ī. —						e	
	Cardiac Pediatric .				Ī				
Cardiac	Intravascular (Cardiac)				<u> </u>				
	Trans-exoph.(Cardiae)	1	1						
	Intra-Cárdiac					T	1 12.1		
Peripheral	Peripheral Vascular						7 7 7		giera (j. 56
Viscular	Other (specify)	-	- 1		7 in	1	72.		

Additional comments:Combined modes: B+M, PW+B; Color + B; Power + B, PW +Color+ B, Po

- *lutrapperative includes abdominal, thoracic, and vescular etc.
- **Small organ-breast, thyroid, testes, etc.
- **Small organ-breazt, thyroid, testes, etc.
- ***Other use includes Urology.
- Note 1: Tissue Harmonic Imaging.
- Note 2: Smart3D
- Note 3: IScape
- Note4: iBeam
- Notes: Blopsy Guidance
- Notes: Proc Xros M
- Note7: 4D

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of in Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

System: -

DC-3/DC-3T Diagnostic Ultrasound System

Transducer:

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

i i i i i i i i i i i i i i i i i i i	Clinical Application			71.7		Mode	of Operation		
General (Track I Only)	Specific (Track 1 & 3)	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								New Year
	Feral					1			
4.4	Abdominal	P	p	P		р	P	P	Note 2,3,4,5,6
	Intraoperative (specify)*								
	Intraoperative (Neuro)					1.			
	Laparoscopic								-
	Pediatric	P	P	Р		l P	P	p - 2	Note 2,3,4,5,6
Fetal	Small organ(specify)**	P	P	Р		P	Р	P	Note 2,3,4,5,6
rcia: Imaging	Neonatal Cephalic	P	P	P		P	P	P	Note 2,3,4,5,6
& Other	Adult Cephalic					1877			*
w ony	Trans-rectal								
•	Trans-vaginal					<u> </u>	-		
	Trans-urethral		\vdash			1			
	Trans-esoph (non-Card.)							مريا مسافات في سي	
	Musculo-skeletal Conventional	P	P	P	is	P	Р	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P	makay sa	P	P	P	Note 2,3,4,5,6
	Intravascular				******	,,,	10.7	1.00	
	Other (specify)***		-						
	Cardisc Adult								
	Cardiac Pediatric					I			
Cardiac	Intravascular (Cardiac)								*
144	Trans-esoph.(Cardiac)		. i.az						in the second
. Finidel	Intra-Cardiac					1,000		1	
Peripheral	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6
Vascular	Other (specify)			7	* ****	7 7 1			

N-new indication; P-previously cleared by FDA; E-added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D Note 3: iScape

Note4: iBeam

Notes: Biopsy Guidance

Notes: Free Xros M

Note7: 4D

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

DC-3/DC-3T Diagnostic Ultrasound System

Transducer.

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

10.40	Clinical Application					Mode	of Operation	**************************************	
General (Track I Only)	Specific (Track 1-& 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal .					1			
	Abdominal	p	'n	p		р	P	P	Note 2,3,4;5,6
i karlı İdaylı Türktüğül	Intraoperative (specify)*	****	-		i				
	Intraoperative (Neuro)					1		 	
-	Laparoscopic	i	T -			 			<u> </u>
	Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
Fetal Imaging & Other	Small organ(specify)**	P	P	P		P	P	P	Note 2,3,4,5,6
	Neonatal Cophalic	P	P	P		P	P	P	Note 2,3,4,5,6
	Adult Cephalic				į.				
~ Ou	Trans-rectal								
	Trans-vaginal	17 mm 1.1 m 17 mm 1.1 m				1	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
	Trans-arcthral			***					
	Trans-esoph (non-Card.)	* 1							
	Musculo-skeletal Conventional	P	P	P	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	P	P		P	P	, P	Note 2,3,4,5,6
	Intravascular	22				1			
<u> </u>	Other (specify)***		,					e e e e e e e e e e e e e e e e e e e	
	Cardiac Adult		1	111	,				•
	Cardiac Pediatric					1			
Cardiac	Intravascular (Cardiac)		1			<i>'</i>			
	Trans-esoph.(Cardiac)						4		
ga V	Intra-Cardiac								
criphcral	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6
/ascular	Other (specify)	140	P4 - 7 - 7						

N=new indication: P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B

- *Intraoperative includes abdominal, thoracic, and vascular etc.
- **Small organ-breast, thyroid, testes, etc.
- ***Other use includes Urology.
- Note 1: Tissue Harmonic Imaging.
- Note 2: Smart3D
- Note 3: iScape
- Note4: iBeam
- Note5: Biopsy Guidance
- Notes: Free Xros M

Note7: 4D

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System

Transducer: 10L4

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		:		***************************************	Mode	of Operation		
General (Track I Only)	Specific (Track (-&3).	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify).	Other (specify)
Ophthalmic	Ophthalmic		11 25-27 1						V V.M.C.1
9.*:: 11	Fetal					1	a in it is a second		
	Abdominal	P	P	P		P	P	P	Note 2,3,4,5.6
	Intraoperative (specify)*				1				
	Intraoperative (Neuro)				·		-		
	Laparoscopic				·	····			
	Pediatric	P	Р	P	 	Р	p ., 46	P	Note 2,3,4,5,6
	Small organ(specify)**	P	P	P		'P	P ^{ill}	p'	Note 2,3,4,5,6
Fetal Imaging	Neonatal Cephalic	P	Р	P		P	P	p .1	Note 2,3,4,5,6
A Other	Adult Cephalic				,				
	Trans-rectal		7 137					7.	
	Trans-vaginal						1.5. 5.4	- 10 Table 1	
	Trans-urethral							***************************************	
	Trans-esoph.(non-Card.)	3			************				
	Musculo-skeletal Conventional	P	· P	P		Р	P	P	Note 2,3,4,5,6
	Musculo-skeletał Superficial	P	P	P		P	P	P	Note 2,3,4,5,6
	Intravescular		·						
	Other (specify)***		,		:				
	Cardiac Adult .				-		-		
	Cardiac Pediatric						*		
Cardisc	Intravascular (Cardiac)						ئى ئارىلى ئىرىنى		
	Trans-esoph (Cardiac)						k. fg.		
ri dhassad	Intra-Cardiac	Ĺúiu	i i	, is			ou conto di		
Peripheral	Peripheral Vascular	P	P	p.		P	P8.11	P	Note 2,3,4,5,6
Vascular	Other (specify)	A	255,5			T The second			

N=new indication; P=previously cleared by FDA, E=added under Appendix E.

Additional comments: Combined modes: B+M, FW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

** Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Nates: Free Xros M

Note7: 4D

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K H102865

Diagnostic Ultrasound Indications for Use Form

System: DC-3/DC-3T Diagnostic Ultrasound System

Transducer: 6C2

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				•	Moder	f Operation	in the second	
General (Track:I Only)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combine d (specify)	Other (specify)
Ophthalmic	Ophthalmic								
They shalp to the	Petal	21							1,
,	Abdominal	P	P	P		P	P	Þ	Note 2, 3,5,6
٠.	Intraoperative (specify)*					1		_	
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	Р.,	P	P		P	P	P	Note 2, 3,5,6
	Small organ(specify)**								
Fetal	Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3,5,6
Imaging	Adult Cephalic	P	P	P		P	P	P	Note-2, 3,5,6
& Other	Trans-rectal		11.2			,			
	Trans-vaginal							r,	
	Trans-urethral								
	Trans-esoph.(non-Card.)		,						*
•	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial								
	Intravascular								1
	Other (specify)***	P	P	P		P	P	P	Note 2, 3,5,6
	Cardiac Adult	P	P	P		P	ĸP.	P	Note 2, 3,5,6
	Cardiac Pediatric	P	P	P		P	P	Ρ.	Note 2, 3,5,6
Cerdiac	Intravascular (Cardiac)							. u	
	Trans-csoph.(Cardiac)		773-1						
	Intra-Cardiac		1				<u> </u>		
Peripheral	Peripheral Vascular								
Vascular	Other (specify)						—		

N=new indication; P=previously cleared by PDA; E=added under Appendix E

Additional comments: Combined modes: 8+M, FW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, stc.

***Other use includes Urology.

Note in Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: (Beam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K_K102865

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Transducer:

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		2.			Mode	of Operation	,	
General (Track I Only)	Specific (Track, I & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic.	Ophthalmic			Grafian i					
	Feal 1	Ρ.	P	P		P	p :	, p	Note 2,3,4,5,6
	Abdominal			81, Ar. 118	(10) - 1		is made big		
	Intraoperative (specify)*				<u> </u>			<u> </u>	
	Intraoperative (Neuro)								
	Laparoscopic:								· · · · · · · · · · · · · · · · · · ·
	Pediatric	-,,-			· ·	<u> </u>			
	Small organ(specify)**		_			 			
Fetal Imaging & Other	Neonstal Cephalic						52 S 187 A		1.0
	Adult Cephalic	174							
or Onto	Trans-rectal	P	P	P		Р	Р	P P	Note 2,3,4,5,6
N. 11	Trans-veginal			19	or egal	2 17 1 2 10	17 19		
	Trans-urethral								, , , , , , , , , , , , , , , , , , , ,
	Trans-esoph (non-Card.)				Ť				
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial						1		
	intravasçular								
	Other (specify)***	P	P	P		P	P	P	Note 2,3,4,5,6
	Cardiac Aduli		7-5	14			1.6		
	Cardiac Pediatric		1						
Cardiac	Intravascular (Cardiac)				.41,			Million & A	
3.05	Trans-esoph (Cardiac)			1,77					Yelli Yelli
ļ. P	Intra-Cardiae							. 1947 T. 1	
Peripheral	Peripheral Vascular								en e
Vascular	Other (specify)					T			

N-new indication; P-previously cleared by FDA: E-added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW + Color+B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1; Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Transducer:

6LB7

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					Mode	of Operation		
General Track I Only)	Specific (Track I.& 3)	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
,	Fetal			b					
	Abdominal					· · · · · ·			
	Intraoperative (specify)*								
	Intraoperative (Neuro)		,				1 1	16.401.80	
	Laparoscopic	× .	,		s oran Again				
	Pediatric								
Fetal	Small organ(specify)**								
	Neonatal Cephalic		ļ						
imaging & Other	Adult Cephalic				1			7	
e Outer	Trans-rectal	P	Р	P		P	P	P	Note 2,3,4,5,6
	Trans-vaginal		 		^:				
	Trans-urethral			T	N 200	,		10.0	1.1.1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
k Han Ha	Trans-esoph (non-Card.)								and the second
	Musculo-skeletal Conventional								
	Musculo-skeletal Superficial				100	1 4	- 1		14 T
*	Intravascular								and the second
	Other (specify)***	Р.	P	P		P	P	·P	Note 2,3,4,5,6
	Cardiac Adult								
F	Cardiac Pediatric						-1		
Cardiac	Intravascular (Cardiac)								
	Trans-esoph (Cardiac)		<u> </u>		7 -				
	Intra-Cardiac		Π	Τ		T		1, 15	
Peripheral	Peripheral Vascular		T .						ni i
Vascular	Other (specify)		1	10 10					Constant

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Notes: Free Xros M

Note7: 4D

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Division of Radiological Devices

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Transducer:

3Ci

intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					Mode o	f Operation		
General (Track I Only)	Specific (Track (& 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combine d (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal				(14)			Gardia I di S	
	Abdominal	P	P	P		P	P	P	Note 1,2,3,5,6
	Intraoperative (specify)*			1 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3		ř.			1. 1.
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	Р		P	P	P	Note 1,2,3,5,6
Α.	Small organ(specify)**								```
etal	Neonatal Cephalic		1.87						
Imaging	Adult Cephalic				1		1 1 1		r i yan
k Other	Trans-rectal				At yet				
	Trans-vaginal	3 h			*				
	Trans-urethral		**	1 16 6					
	Trans-esoph (non-Card.)		Ľ	1					
	Musculo-skeletal Conventional					<u> </u>			
	Musculo-skeletal Superficial							7	
	Intravascular						*		
illidation of the	Other (specify)***	1							مرافأ مرز بالمراد
	Cardiac Adult	P	P	P		P	ľ	P"	Note 1,2,3,5,6
	Cardiac Pediatric	P	P	P		P	P	P	Note 1,2,3,5,6
Cardiac	Intravascular (Cardisc)				.				
ia 1	Trans-esoph (Cardiac)			· .					
	Intra-Cardiac					T .	1		
'cripheral	Peripheral Vascular		1 - 1 - 1						
Vascular	Other (specify)			4				. ,	

N=new indication; P=previously cleared by FDA; E=added under Appendix E ...

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B;

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes; etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Noted: Free Xros M

Note7: 4D

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Transducer

7P2

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			· · ·	11.000000	Mode o	of Operation		
General (Track I Only)	Specific (Track I & 3)	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic					,			
	Petal					, y			
· .	Abdominal .	P	P	P	P	P	P	P	Note 1, 2,5,6
	Intraoperative (specify)*	^ : ·							
	Intraoperative (Neuro)		esti i						i i
	Laparoscópic			K					ini ca
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,5,6
· · · · · · · · · · · · · · · · · · ·	Small organ(specify)**								Parks North Control
Fetal	Neonatal Cephalic	. P	P	P	P	P	P	P	Note 1, 2,5,6
Imaging	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,5,6
& Other	Trans-rectal								* *
	Trans-vaginal							3	
	Trans-urethral				,				
	Trans-csoph (non-Card.)			1			3 i.e		
	Musculo-skeletal Conventional	3. K	2 (in a li n an	i jar			
	Musculo-skeletal Superficial	Sec. 4							
e está.	Intravascular								
	Other (specify)***								
. 200	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,5,6
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,5,6
Cardiac	Intravascular (Cardiac)								
	Tranś-csoph (Cardiac)			1					
ika sa	Intra-Cardiac		,				1 1		
Peripheral	Peripheral Vascular	rigaria):		1	Britan (Ideo)	ar garanos ir Silanis		-	
Vascular	Other (specify)			1	1	1.		 	

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.
Note 1: Tissue Harmonic Imaging.

Note 2: SmarGD

Note 3: iScape

More 3: 12cabe

Note4: iBesm"

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102865

Diagnostic Ultrasound Indications for Use Form

System:

DC-3/DC-3T Diagnostic Ultrasound System

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

			1 20		Mode	of Operation			
General (Track 1 Only)	Specific (Track I & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal					\$ 3000 C 100			
	Abdominal	P	P	Р		P	P	P	Note 2,3,4,5,6
	Intraoperative (specify)*		\						
	Intraoperative (Neuro)	*		1				***************************************	
	Laparoscopic								<u> </u>
	Pediatric	P	P	P		P	P	P	Note 2,3,4,5,6
Fetal	Small organ(specify)**	P	Р	P	3	P	P	P	Note 2,3,4,5,6
retat Imaging & Other	Neonatal Cephalic	P	P	P		P	P	Р	Note 2,3,4,5,6
	Adult Cephalic	400							i Colina
	Trans-rectal								
	Trans-vaginal			13.0		i.	7.70		v " vedala
•	Trans-urothral			11.11					3.4
	Trans-esoph (non-Card.)		1			- /			
	Musculo-skeletal Conventional	Ρ.	P	P		P	P	P	Note 2,3,4,5,6
	Musculo-skeletal Superficial	P	Ρ.	P		P	P	P	Note 2,3,4,5,6
	Intravascular			l			-		,
	Other (specify)***		e ta		,				
· · · · · · · ·	Cardiac Adult			incli	المارية		s is it will be	ilini Albuma I a a	
Cardiac	Cardiac Pediatric			13.00					
	Intravascular (Cardiac)						· Jag skill	3 1 1	
	Trans-esoph (Cardiac)				1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	. ,			10.71
	Intra-Cardiac	· [1.5			, <u> </u>		
•	Peripheral Vascular	P	P	P		P	P "	, P	Note 2,3,4,5,6
Vascular	Other (specify)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments Combined modes: B+M, PW+B, Color + B, Power + B, PW,+Color+B, P

*Intraoperative includes abdominal, thoracic, and vascular etc.

.**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology. Note to Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

DC-3/DG-3T Diagnostic Ultrasound System

7LT4

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
) Ophthalmic	Ophthalmie	i di sidi		i ila							
Fetal Imaging & Other	Fetal		X(\$#16		,	11,000,000,00		.			
	Abdominal	P	P	p	1	P	P	P	Note 2,3,4,5,6		
	Intraoperative (specify)*	P	P	P		P	P	Р	Note 2,3,4,5,6		
	Intraoperative (Neuro)			,							
	Laparoscopic	-				<u> </u>					
	Pediatric	Р	P	P		P	P	P	Note 2,3,4,5,6		
	Small organ(specify)**	P	P	Р		P	P	Р	Note 2,3,4,5,6		
	Neonatal Cephalic	P	р	P		P	1 p 1	Р	Note 2,3,4,5,6		
	Adult Cephalic	10000		roles co	angyay nga	1					
	Trans-recial			K U							
	Trans-yaginal	7.75	- "		2.						
	Trans-urethrai		-		,						
	Trans-esoph (non-Card.)		٠								
	Musculo-skeletal Conventional	P	P	P		P	P	Р	Note 2,3,4,5,6		
	Musculo-skeletal Superficial	P	·P	P		P	P	P	Note 2,3,4,5,6		
	Intravascular						Property (1)				
1	Other (specify)***						jalangki na i				
	Cerdiac Adul	Р	P	P		P	P	Р	Note 2.3,4.5.6		
Cardiac	Cardiac Pediatric	P	P	Р	200	P	9	P	Note 2,3,4,5,6		
	Intravascular (Cardiac)		1	2017 27 27		1		 			
	Trans-esoph (Cardiac)					1					
	Intra-Cardiac	, ,					l		<u> </u>		
eripheral	Peripheral Vascular	P	P	P		P	P	P	Note 2,3,4,5,6		
Vascular	Other (specify)	ļ	1								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intrapperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note I. Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: iBeam

Note5: Biopsý Guidance

Note6: Free Xros M

Note7: 4D

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

Systém: DC-3/DC-3T Diagnostic Ultrasound System

Ťransducer: D6-2

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

f 22.00000	Clinical Application					Mode	of Operation		
General (Track I Only)	Specific (Track & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Felal	P	P	P		Р	P	P	Note 1, 2, 3,6,7
	Abdominal .	₽	P	P		P	.È.	, Р	Note 1, 2, 3,6,7
	Intraoperative (specify)*			- N					
	Intraoperative (Neuro)	37.7							
	Laparoscopic	<u> </u>	-	 	1				1940 W 10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	Pediatric	P	P	P		P	P	P	Note 1, 2, 3,6,7
	Small organ(specify)**	<u> </u>	 	╌			 	-	11000 1, 2, 0,0,1
Fetal	Neonatal Cephalic	-	-	 	. •				
Imaging & Other	Adult Cephalic		,				3.0		in the state of
	Trans-recial		· · · · · · ·						
	Trans-vaginal	1103 27 1 57		11111	21/2 (4.3	<u> </u>			
41.4	Trans-urethral		П	1					
	Trans-esoph.(non-Card.)	7 77		1		T			
	Musculo-skeletal Conventional		1		,	· · · · · · · · · · · · · · · · · · ·			
<u></u>	Musculo-skeletal Superficial		1						
	Intravascular				k	T	,		42. 3.5
1. 1.4 3.4	Other (specify)***	de C				i	a waa fada b	on t	u a anglikati
	Cardiac Adult					S			
	Cardiao Pediatric				KONNECTOR				
Cardiac	Intravascular (Cardiac)						1 - 6 4		1
170	Trans-esoph (Cardiac)								
*	latra-Cardiac								
	Peripheral Vascular	:							
Vascular	Other (specify)			Г	£	l		,	

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

***Other use includes Urology.

Note I: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3: iScape

Note4: (Beam

Note5: Biopsy Guidance

Note6: Free Xros M

Note7: 4D

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